

PRODUCT: MEXILETINE HCl USP

FDA Labeler Code No. 053296

Certificate of Analysis No. : 18A0090/02

Lot No. : A-180086

Quantity. : 10 KG

ANALYTICAL DATA	SPECIFICATIONS	RESULTS	NOTES
Description	White or almost white crystalline powder.	Conforms	
Identification	Test A.- IR, Test B.- HPLC - Assay and Test C.- Chloride identification.	Conforms	
pH	3.5 - 5.5 (solution 1 in 10)	5.5	
Loss on Drying	NMT 0.5%	0.06 %	
Residue on ignition	NMT 0.1%	Less than 0.05 %	
Chromatographic purity. Impurity MXT-200	NMT 0.10%	0 %	Not Detected
Chromatographic purity. Impurity MXT-300.	NMT 0.10%	0 %	0,00%
Chromatographic purity. Any other individual impurity	NMT 0.10%	0 %	0.00%
Chromatographic purity. Total impurities	NMT 1.5%	0.01 %	
Assay	98.0 - 102.0% (on dry basis)	99.5 %	
2,6-Dimethylphenol	NMT 0.1%	Conforms	

Manufacturing Date February 15, 2018

Re-Test date February 15, 2021

Analyst

05.03.18

Head of Quality Control

05.03.18

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